

REMARKS

The Rejections Under 35 USC § 112, first paragraph, written description

The term prodrug is removed from the rejected claims. However new claims 39-42 are added which recite prodrugs. Thus, the following comments are provided on this issue.

Claims 39-42 are directed to methods reciting the prodrugs of a finite number of specific compounds, including the more specific prodrugs described in the specification being recited in dependent claims.

The Office Action correctly identifies the description of prodrugs of the claimed compounds in the specification, including the more specific embodiments thereof, but nevertheless rejects the claims as having insufficient written description.

“The test for determining compliance with the written description requirement is whether the disclosure of the application as originally filed reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter.” See *In re Kaslow*, 217 USPQ 1089 (CAFC 1983), citing *In re Edwards*, 558 F.2d 1349, 196 USPQ 465 (CCPA 1978) and *In re Herschler*, 591 F.2d 693, 200 USPQ 711 (CCPA 1979).

In addition to the description in the specification, one of ordinary skill in the art knows generally what a prodrug is, and especially in a situation where a finite number of specific compounds are at issue, as the case herein, can readily envision the types of prodrugs possible. Moreover, the types of prodrugs possible can be easily tested in a variety of tests/models to see whether the recited compounds result therefrom. Thus, one of ordinary skill in the art would understand from the disclosure that the inventors of the present application had possession of the claimed matter.

Moreover, there is no reason for restricting the claims to the specific prodrugs mentioned as examples thereof in the specification, since the invention is not so restricted or limited. See, e.g., *Falkner v. Inglis*, 448 F.3d 1357, 79 USPQ2d 1001 (Fed. Cir. 2006), and *Capon v. Eshhar*, 418 F.3d at 1357, 76 USPQ2d 1078 (Fed. Cir. 2005), in support.

In *Falkner* the invention related to “a way of making vaccines safer by deleting or inactivating an *essential*, rather than an inessential, gene from the viral vector's genome.” The approach was taught to be applicable to many different kinds of vector viruses. Detailed description of only the herpes virus was present in the specification, with pox virus being mentioned. The specification did not identify any *essential* genes in pox virus or describe the inactivation of such *essential* genes. Moreover, the specification specifically admitted that vaccines were not produced with pox virus. The claimed invention was however directed to

the making of a vaccine with a pox virus. A written description rejection followed. The Federal Circuit decided that:

[W]e hold, in accordance with our prior case law, that (1) examples are not necessary to support the adequacy of a written description (2) the written description standard may be met (as it is here) even where actual reduction to practice of an invention is absent; and (3) **there is no per se rule that an adequate written description of an invention that involves a biological macromolecule must contain a recitation of known structure.** (Emphasis added.)

In *Capon* the invention was directed to novel genetic material described in terms of the functional characteristics of the protein it encodes. The specification did not provide a description of the full scope of the chimeric DNA or encoded proteins, but provided procedures for identifying and obtaining the desired immune-related DNA segments and linking them into the desired chimeric genes. A written description rejection followed. The Federal Circuit decided that:

The **Board erred in holding that the specifications do not meet the written description requirement because they do not reiterate the structure or formula or chemical name** for the nucleotide sequences of the claimed chimeric genes.

...
“[I]t must be borne in mind that, while it is necessary that an applicant for a patent give to the public a complete and adequate disclosure in return for the patent grant, the certainty required of the disclosure is not greater than that which is reasonable, having due regard to the subject matter involved.” (Emphasis added.)

For all the foregoing reasons, reconsideration is requested.

The Rejections Under 35 USC § 112, first paragraph, enablement

Applicants respectfully disagree with the rejection, but to advance prosecution toward allowance, decided to amend the claims to render this rejection moot by removing the term “prophylaxis” from the claims.

Obviousness-type Double Patenting Rejection

US 10/541,493 does not teach or suggest the specific compounds recited in the present claims. In its narrowest disclosure, the claims of the reference include compounds with R₂ or R₃ being thiol generally. However, this broad disclosure is not adequate to render obvious the specific compounds recited in the present claims with specific thiol groups.

The Rejections Under 35 USC § 102

The claims are rejected as allegedly anticipated by US 6,323,240 as evidenced by US 6,572,542.

The current method claims are directed to specific 2-... thio-...-oxobutanoic group containing compounds. Neither reference teaches or suggests the specific compounds recited in the claims.

US '240 in its broadest disclosure recites thiol as one of the many options for any of R₁ through R₄. However, not a single compound with a thiol group is taught in the disclosure of the reference, which includes all the thiol groups of all the specific compounds of the present claims.

Alkylthio is also an option for R₁ through R₄, and a specific compound with either R₁ or R₃ being thiomethyl is prepared (see column 5, line 47), however, the claims of the present application do not recite alkylthio groups in the corresponding position.

Withdrawal of this rejection is respectfully solicited.

New Compound Claim

The new compound claim recites the compounds also recited in the method claims. Applicants request the examination of this new compound claim too. The examination of this claim would not pose an undue search burden on the USPTO.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

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